

REMARKS

Claims 1-10 were presented for examination in the present application. The instant amendment cancels claim 11 and adds new claims 17-19. Thus, claims 1-10 and 12-19 are presented for consideration upon entry of the instant amendment. Claims 1, 12, and 17 are independent.

Rejections to claims 1-11

Independent claim 1, as well as dependent claims 2-11, were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,059,109 to Tischlinger et al. (Tischlinger).

Applicants submit that amended claim 1 is not disclosed or suggested by Tischlinger.

Independent claim 1 has been clarified to include elements of claim 11, which has been cancelled. Further, claim 1 has been amended to recite that "both pistons may be interconnected and displaced in common to cause a pressure increase both in the active agent chamber and the gas chamber and to feed the active agent and the gas to the foam producing means (emphasis added)".

Tischlinger fails to disclose a gas chamber as recited by claim 1. Rather, the element asserted by the Office Action is disclosed by Tischlinger as being a second chamber 22 for dry medicament. See col. 1, lines 60-65.

Further, Tischlinger fails to disclose or suggest foam producing means as recited by claim 1. Rather, the element asserted by the Office Action is disclosed by Tischlinger as being a cannula 164. See col. 3, lines 20-25. Applicants submit that cannula 164 is simply not suitable for producing foam. Even if one were to assume that the skilled person would replace the dry medicament in chamber 22 of Tischlinger with a gaseous component, it has to be considered that high shearing forces are required in order to produce foam. If foam shall be produced during the passage of the two

components through the cannula 164, these components must be pressed through this cannula with high pressure and velocity, so that high shearing forces can be generated. However, this is not possible, since according to column 3, lines 45-47 of Tischlinger "the cannula 164 should be introduced into the locus to receive the medicament whereupon the plunger 14 is moved forward". Pressing the two components with a high pressure and velocity through needle 164, as it is required for generated high shearing forces, would lead to an injury of the patient.

Also, even if one were to assume that the dry medicament in chamber 22 of Tischlinger was a gas, the two components would not intermingle after the component A has been introduced into chamber 22 through the needle 100, since only component A is transmitted through needle 100. Therefore, the two components would exist in chamber 22 as separated phases. Depending on the position of the syringe, these two separated phases do not intermingle to a relevant extent during the passage through the cannula 164. Rather, they leave needle 164 as separated phases, making it impossible to produce a foam. If cannula 164 should function as a foaming element, the two components have to arrive at the needle together at the same moment and in a defined ratio. Therefore, the device according to Tischlinger is not suitable for producing any foam and in particular for producing a medicinal foam.

In sum, Tischlinger simply fails to disclose or suggest the "gas chamber" and "foam producing means" recited by claim 1.

Notwithstanding the above, the amendments made to claim 1 further distinguish from Tischlinger. Again, claim 1 now recites that both pistons are "interconnected and displaced in common to cause a pressure increase both in the active agent chamber and the gas chamber".

In contrast, Tischlinger discloses a shifting of both pistons only occurs when piston 60 abuts on the second piston 90, so that both pistons can be displaced together. Please note that at this moment, chamber A does not exist anymore and therefore a

pressure in this chamber cannot be increased. Thus, the common displacement of both pistons in the Tischlinger device leads only to an increase of the pressure in one of the chambers, namely in chamber 22, so that Tischlinger fails to disclose or suggest present claim 1.

Accordingly, reconsideration and withdrawal of the rejection to claims 1-10 over Tischlinger are respectfully requested.

Independent claim 1, as well as dependent claims 6 and 8, were also rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,538,920 to Drake (Drake).

Claim 1 recites "a gas chamber closed with a second piston (emphasis added)".

Drake does not use a gaseous component, therefore making a foam production impossible. Instead, column 3, lines 12-15 describes that each of the chambers of the Drake device are each filled with one part of a two-part polymerizable material.

Further, Applicants submit that the inclusion of elements of claim 11 into claim 1 obviates the §102(b) rejection to claim 1 over Drake. Specifically, claim 1 now recites that the gas chamber and the active agent chamber are "arranged one after another".

Accordingly, reconsideration and withdrawal of the rejection to claim 1, as well as claims 2-10 that depend therefrom, over Drake are respectfully requested.

Independent claim 1, as well as claims 2 and 5-10, were rejected under 35 U.S.C. §103 over U.S. Publication No. 2002/0101785 to Edwards et al. (the Edwards '785 publication) in view of U.S. Patent No. 5,454,805 to Brony et al. (Brony). Dependent claims 3-4 were rejected under 35 U.S.C. §103 over the Edwards '785 publication in view of U.S. Patent No. 2,724,383 to Lockhart (Lockhart).

Applicants respectfully maintain the traversal of this rejection.

Claim 1 recites "a **foam producing means** connected with the active agent chamber and the gas chamber".

The Office Action acknowledges that the Edwards '785 publication fails to disclose a foam producing means. Rather, the Office Action asserts that Brony discloses the use of a sieve. Further, the Office Action asserts that although Brony only discloses the mixture of two liquids, a gas component could be combined through the sieve.

The Edwards '785 publication does not disclose a device for producing medicinal foam but instead is related to an apparatus for mixing a liquid component and a powdered component to form a bone filler. Again, no gaseous component is used so that foam production is not possible.

A skilled person would not replace the powdered component of the Edwards '785 publication with a gaseous component, since this would render the production of a bone filler impossible. For the same reason, the skilled person would not use a foam producing means in combination with the device of the Edwards '785 publication, even if such a foam producing means is known from the state of the art, since the use of such a foam producing means would again make the production of a bone filler impossible.

Even if a skilled person would use one of the chambers of the device disclosed by the Edwards '785 publication for a gaseous component, Edwards fails to describe at which place of the device a foam producing means could be arranged so that the production of foam is made possible. Therefore, the skilled person would not find the inventive features of recited by claim 1.

In sum, the Office Action attempts to modify the device of the Edwards '785 publication (mixes solid and liquid) with the sieve in the device of Brony (mixes two liquids), then further modifies this combination by using a gas, where such a combination would render the device of the Edwards '785 publication unsuitable for its

intended purpose.

Furthermore, Applicants maintain that the Edwards '785 publication is non-analogous art to the Brony and Lockhart references such that the proposed combination of cited art fails to disclose or suggest claim 1.

Still further, claim 1 now recites, in part, that "both pistons may be interconnected and displaced in common to cause a pressure increase both in the active agent chamber and the gas chamber and to feed the active agent and the gas to the foam producing means".

The Edwards '785 publication discloses that handle 34 is moved back and forth to mix the components meaning that as the pressure is increased in one chamber, it is decreased in the other.

Accordingly, present claim 1, as well as claims 2-10 that depend therefrom, are not disclosed or suggested by the proposed combination of cited art. Reconsideration and withdrawal of the rejection to claims 1-10 over the Edwards '785 publication alone or in combination with Brony and Lockhart are respectfully requested.

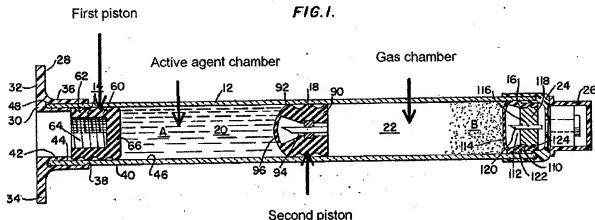
Rejections to claims 12-16

Independent claim 12, as well as dependent claims 13-16, were rejected under 35 U.S.C. §102(b) over Tischlinger.

Applicants submit that amended claim 12 is not disclosed or suggested by Tischlinger. Independent claim 12 has been clarified and now recites "an active agent chamber closed with a first piston" and **"a gas chamber closed with a second piston and closed with the first piston"** (emphasis added)".

The Office Action assert that first chamber 20 reads on the claimed **"active agent chamber"**, second chamber 22 reads on the claimed **"gas chamber"**, circular

body 60 of plunger 14 reads on the claimed "**first piston**", and body portion 90 of diaphragm assembly 16 reads on the claimed "**second piston**". For ease of analysis, Figure 1 is reproduced below have each of the elements asserted by the Office Action as reading on these claimed elements marked.



As can clearly seen from the marked version of Figure 1, the second chamber 22 of Tischlinger is clearly not closed by plunger 14.

Thus, Applicants submit that Tischlinger fails to disclose or suggest the claimed first piston that closes both the active agent chamber and the gas chamber as recited by present claim 12.

Accordingly, present claim 12, as well as claims 13-16 that depend therefrom, are not disclosed or suggested by the proposed combination of cited art. Reconsideration and withdrawal of the rejection to claims 13-16 over Tischlinger are respectfully requested.

New claims 17-19

Applicants wish to thank the Examiner for his suggestions regarding suggested subject matter that distinguishes over the art of record. To that end, claims 17-19 have been added to point out various aspects of the present application. Support for new

claims 17-19 can be found at least in original claims 1-10, as well as in the specification at page 5, line 7 through page 7, line 26. No new matter is added

Applicants specifically point out that new claims 17-19 are not intended to be limited to the specific mechanisms of patentability previously argued with respect to any previously claim. Accordingly, Applicants hereby rescind any disclaimer of claim scope and, thus, any prior art for which such a disclaimer was made to avoid may need to be revisited by the Examiner with respect to new claims 17-19.

It is believed that new claims 17-19 are in a condition for allowance. For example, independent claim 17, in part, recites "a first piston closing the open top end of the active agent carpule and the bottom end of the gas chamber". In addition, independent claim 17 recites that "upon displacement of the second piston to a point where the hollow needle pierces through the first piston and the entrainment element contacts the first piston, the entrainment element maintains a distance between the first and second pistons to allow a pressure increase in both the active agent chamber and the gas chamber so that the active agent and the gas are fed to the foam producing means".

Applicants submit that the cited art fails to disclose or suggest both the "first piston" and the "entrainment element" in the manner recited by claim 17. Accordingly and for at least these reasons, claim 17, as well as claims 18-19, are each patentable over the cited art.

Summary

In view of the above, it is respectfully submitted that the present application is in condition for issuance. Such action is solicited.

If for any reason the Examiner feels that consultation with Applicants' attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

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